Guidelines for Pharmaceutical Sections

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A separate pharmaceutical section is needed for each agent (investigational and/or commercial) used in a DCTD sponsored clinical trial. Pharmaceutical information should be as comprehensive as possible. Extraneous information can lead to errors and should NOT be included. The amount of information required is dependent on the supplier of the agent, e.g. investigational vs. commercial agent.

Investigational agents:

Investigator's should refer to the *NCI Investigational Drug: Pharmaceutical Data 1994* booklet, the pharmaceutical data sheet or the appropriate clinical brochure for agent information.

- **Product description**: Include the agent's NSC #, available dosage forms, ingredients and packaging as appropriate. Also state the agent's supplier, i.e.. investigational product supplied by DCTD.
- **Preparation (how the dose is to be prepared)**: Include reconstitution directions and directions for further dilution if appropriate.
- **Storage requirements**: Include the storage requirements for the original dosage form, reconstituted solution and final diluted product, as applicable.
- **Stability**: Include the stability of the original dosage form, reconstituted solution and final diluted product, as applicable.
- **Route of Administration**: Include a description of the method to be used and the rate of administration if applicable. For example, continuous intravenous infusion over 24 hours, short intravenous infusion over 30 to 60 minutes, intravenous bolus, etc. Describe any precautions required for safe administration.
- **Toxicities**: List all toxicities included in the most recent DCTD toxicity list. Note: The Informed Consent document should contain a list of all known toxicities that the patient is likely to experience. All toxicities should be written in laymen's terms.

Commercial Agents:

Investigators should refer to the package insert for agent information.

- **Product description**: State the agent's supplier, i.e. commercially available.
- **Preparation (how the dose is to be prepared)**: Investigators may refer the reader to the package insert for 'standard' preparation instructions. If the agent is to be prepared by 'non-standard' or protocol specific fashion, the reconstitution directions and instructions for further dilution must be included. Appropriate storage and stability information should be included to support the method of preparation.
- **Route of Administration**: Briefly describe how the agent will be administered. For example, continuous intravenous infusion over 24 hours, short intravenous infusion over 30 to 60 minutes, intravenous bolus, etc.
- **Toxicities**: The investigator may refer the reader to the agent's package insert. Note: The Informed Consent document should contain a list of all known toxicities that the patient is likely to experience. All toxicities should be written in laymen's terms.